# EXHIBIT I

# Contemporary Comparison Between Retropubic Midurethral Sling and Autologous Pubovaginal Sling for Stress Urinary Incontinence After the FDA Advisory Notification

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**OBJECTIVE** To compare the efficacy and safety in a contemporary cohort of women who were offered either a pubovaginal sling (PVS) or a synthetic midurethral sling (MUS) after the US Food and Drug Administration notification and made an informed decision on procedure option.

**METHODS** A total of 201 women were given the option between a PVS and an MUS. Prior anti-incontinence surgery and concomitant surgery other than hysterectomy were not allowed. Minimal follow-up was 12 months. Patients were prospectively followed with validated quality of life questionnaires. Cure, voiding complaints, and complications were compared between the groups.

**RESULTS** Ninety-one women (45%) underwent PVS and 110 underwent MUS (55%). Median follow-up was 13.8 months. There was no difference in baseline characteristics between the groups except for the prevalence of urge incontinence. Subjective improvement in questionnaire scores was significant for both groups. Cure rate was accomplished in 75.8% of the PVS group patients compared with 80.9% of the MUS group patients (hazard ratio, 1.35; 95% confidence interval, 0.69-2.7; $P = .38$). Complications and voiding difficulty were similar between the groups.

**CONCLUSION** In this contemporary cohort of women considered suitable candidates for either a PVS or an MUS, both offer comparable efficacy and complication rates. PVS may be safely offered to patients who would otherwise be good candidates for MUS if they are concerned with the implantation of mesh. UROLOGY 85: 321–325, 2015. © 2015 Elsevier Inc.

Urinary incontinence (UI) affects up to 50% of women and can result in significant burden medically, socially, and economically.[1] Among these women with UI, 50%-80% are identified as having stress urinary incontinence (SUI),[2] defined by the International Continence Society as "the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing."[3] Although evidence exists in the literature that demonstrates efficacy for nonsurgical treatment,[4] ultimately, an estimated 4%-10% of women in the United States undergo anti-incontinence surgery.[5]

Providing long-term evidence from multiple case series and randomized controlled trials, the American Urological Association guideline from 2009 concluded that synthetic slings are an appropriate treatment choice for women with SUI, with similar efficacy but less morbidity than conventional nonmesh sling techniques, such as a pubovaginal sling (PVS).[6] However, in 2008, a public health notification was issued by the Food and Drug Administration (FDA) to inform patients of adverse events related to placement of surgical mesh in the urogynecology setting. Citing the increasing number of medical device reports along with increasing peer-reviewed scientific literature on mesh, the FDA issued an update in 2011 and identified safety concerns specifically with transvaginal mesh for pelvic organ prolapse (POP).[7] Although a joint position statement recently issued by the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction overwhelmingly supports synthetic midurethral sling (MUS) for the surgical

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treatment of SUI, media attention on all transvaginal mesh has caused confusion and fear regarding MUS.[8]

It has been our practice to offer PVS as well as MUS as a primary surgical option to patients with SUI. In light of the mesh controversy, this practice has taken on new importance and has allowed for a contemporary comparison of efficacy and complication rates in a cohort of women who were offered either a retropubic synthetic MUS or PVS after the FDA notification update in 2011 and made an informed decision on the procedure type.

## METHODS

Between issuance of the FDA update in July 2011 and August 2012, women with the principal complaint of SUI and a positive cough stress test (CST) were offered surgical therapy performed by a single surgeon (A.G.). Exclusion criteria included prior anti-incontinence surgery, prior pelvic surgery other than hysterectomy, need for concomitant surgery other than hysterectomy, concomitant POP greater than Baden-Walker stage 2, neurogenic etiology of incontinence, or urge-predominant mixed UI. This cohort would typically be considered good candidate for a MUS, but it has been our practice (which predates the 2008 FDA notification) to offer a PVS to these women as well because PVS is the gold standard to which MUS is judged and has comparable efficacy. Patient counseling was performed in an unbiased fashion with risks and benefits discussed for each. To the best of our knowledge, no patient or clinical finding swayed our dialogue as the content of the surgical counseling was substantially uniform and routine. For the MUS, specific points highlighted were mesh-related complications such as exposure or extrusion and the possible need for further procedures in these cases. Additionally, after 2008, the FDA public health notification was mentioned, but it was stressed to patients that MUS has the support of the FDA and professional organizations.[8,9] For the PVS, points discussed included the historically higher rates of voiding dysfunction as well as the use of autologous tissue via fascial harvest and its potential pain, wound, and infectious sequelae. After this discussion, the women then chose either a rectus fascia PVS or a retropubic, top-down MUS.

All patients underwent history and physical examination, as well as a supine CST with a full bladder (~300 mL), postvoid residual determination, and voiding diary. The degree of POP was assessed and graded according to the Baden-Walker scale. Urethral hypermobility was recorded if there was a >30° change from baseline to straining. Multichannel urodynamics were performed on all patients and generally comprised medium-fill water cystometry (50 mL/min) using a dual-lumen 8F catheter. The technique, definition, and units of urodynamic measure conform to the standard proposed by the International Continence Society, and patients were allowed to void in the sitting position in privacy.[10]

The operative technique for the PVS has been described elsewhere.[11] Briefly, a 2 × 8 cm strip of rectus fascia is harvested and after vaginal dissection, the endopelvic fascia is perforated, and the retropubic space is entered. Stamey needles or other passers are used to pass the sling sutures from the vaginal area to the suprapubic region. The vaginal incision is closed before sling tensioning, which is accomplished by loosely tying the sutures above the rectus fascia. Once done, 2 fingers can easily be placed between the fascia and the knot. The procedure for the top-down retropubic MUS has also previously been described.[12] Per standard practice, the sling is placed tension free and can easily accommodate a surgical instrument between the urethra and sling. Cystoscopy was performed on all patients to rule out trocar or passer perforation. Vaginal pack and Foley catheter are left in place overnight. In the morning of the first postoperative day, a void trial was given and the vaginal pack was removed.

Patients were prospectively followed using the short forms of the Incontinence Impact Questionnaire and the Urinary Distress Inventory.[13,14] Additionally, a nonvalidated visual analog score (1 [very unhappy] to 10 [very happy]) measuring overall satisfaction with their current condition was recorded. A subjective stress, emptying, anatomy, protection, inhibition (SEAPI) score was also calculated for each patient.[15] Urge UI (UUI) was determined on the basis of a score of >0 on the inhibition portion of the subjective SEAPI score. Follow-up visits were scheduled at 6 weeks, 6 months, and annually. The primary end point was SUI cure and was defined as a score of 0 on the subjective stress subset of the SEAPI (no subjective SUI) as well as a negative CST. De novo UUI was defined as a score of 0 on the preoperative subjective inhibition subset of the SEAPI but a positive score postoperatively. Postoperative voiding difficulty consisted of impaired emptying, urinary retention, and/or obstructive voiding and included patients who required sling incision or catheter use at any point beyond the first postoperative day. Complications within 30 postoperative days were abstracted from the hospital and office records, tabulated, and graded on the basis of the Clavien-Dindo classification on surgical complications.[16]

Preoperative variables were compared between both groups using 2-sample Wilcoxon rank sum test for continuous variables and the Fisher exact test for categorical variables. Median values are provided with an interquartile range. The paired Wilcoxon signed rank sum test was used to calculate significance in subjective questionnaire outcome within each treatment group. Analysis of covariance was performed to test for difference in postoperative questionnaire scores by treatment group after controlling for preoperative scores. Simple logistic regression was used to determine the significance of postoperative outcomes. Multiple logistic regression analysis with patient demographics and preoperative clinical parameters was used to determine if postoperative outcomes differed by procedure type. Total complications were compared using the Fisher exact test between treatment groups as there were too few complications in each class for individual analysis. Criterion for statistical significance was set at $P < .05$. The statistical software program Stata, version 13 (College Station, TX) was used for all statistical analysis.

## RESULTS

Of 201 women who met eligibility, 91 (45%) chose PVS and 110 (55%) chose MUS. This ratio has held constant in our practice, predating the first FDA notification in 2008 (data unpublished). The demographic and clinical characteristics of the patients are listed in Tables 1 and 2. There were no differences with the exception of UUI prevalence, which was more common in the MUS group (86.4% vs 74%; $P = .03$). However, >60% of this is attributed to a score of 1 (rare UUI) from the subjective inhibition subset of the SEAPI score. Restriction of UUI to those patients with at least 1 episode of UUI per week

**Table 1.** Preoperative clinical parameters

| Parameter | PVS, Median (IQR) | MUS, Median (IQR) | *P* Value* |
|---|---|---|---|
| Age, y | 49 (20) | 49 (18) | .72 |
| BMI, kg/m$^2$ | 29.6 (8.3) | 29.6 (9.7) | .48 |
| Pad usage | 1 (3) | 2 (3) | .24 |
| ALPP | 86 (41) | 81 (41) | .25 |
| SEAPI scores | 5 (3) | 6 (3) | .07 |
| IIQ-7 total | 6 (7) | 6 (6) | .72 |
| UDI-6 total | 8 (6) | 9 (5) | .14 |
| VAS | 2.5 (2) | 2 (2) | .87 |

ALPP, abdominal leak point pressure; BMI, body mass index; IIQ-7, Incontinence Impact Questionnaire; IQR, interquartile range; MUS, midurethral sling; PVS, pubovaginal sling; SEAPI, stress, emptying, anatomy, protection, inhibition; UDI-6, Urinary Distress Inventory; VAS, visual analog score.
* Wilcoxon rank sum test.

**Table 2.** Clinical features of cohort

| Feature | PVS, n (%) | MUS, n (%) | *P* Value* |
|---|---|---|---|
| Presence of DO | 9 (10) | 9 (8.2) | .81 |
| UUI prevalence | 67 (74) | 95 (86.4) | .03 |
| Urethral hypermobility | 85 (93.4) | 104 (94.5) | .77 |
| Concomitant hysterectomy | 48 (52.7) | 55 (50) | .78 |

DO, detrusor overactivity; UUI, urge urinary incontinence; other abbreviations as in Table 1.
* Fisher exact test.

yields similar prevalence (32.7% vs 25.3%; $P = .25$). All had a minimum of 1 year of follow-up (median time, 13.8 months; range, 12-25 months). Dysfunctional bleeding and fibroids constituted the indications for concomitant hysterectomy, and no hysterectomy was performed for POP.

Subjective postoperative outcomes are listed in Table 3. There were significant improvements in all questionnaire scores for both groups ($P < .001$). Comparison of each subset of the SEAPI score demonstrated significant differences for the stress, protection, and inhibition components for both treatment groups. There was no difference in postoperative scores by treatment group after controlling for preoperative scores ($P = .67$). SUI cure was accomplished in 69 of 91 women (75.8%) in the PVS group compared with 89 of 110 women (80.9%) in the MUS group (univariate: odds ratio [OR], 1.35; 95% confidence interval [CI], 0.69-2.7; $P = .38$; multivariate: OR, 1.76; 95% CI, 0.7-4.5; $P = .24$). Only 2.2% and 3.6% of the PVS and MUS group patients, respectively, did not have any improvement or cure of their SUI ($P = .3$). Of the treatment failures, 1 patient in each group underwent urethral bulking agent therapy. In those who did not undergo concomitant hysterectomy, univariate logistic regression demonstrated a difference in SUI cure (OR, 3.2; 95% CI, 1.3-7.7; $P = .01$) but not on multiple logistic regression ($P = .239$). De novo (OR, 0.4; 95% CI, 0.09-1.8; $P = .24$), persistent (OR, 1.01; 95% CI, 0.54-1.9; $P = .97$), and resolved UUI (OR, 0.99; 95% CI, 0.52-1.8; $P = .97$) did not differ between the PVS and MUS groups on simple logistic regression (Table 4) or on multiple regression analysis ($P = .7$, 0.98, 0.22, respectively). The length of hospitalization did not differ between groups ($P = .9$) nor did the proportion of patients whose hospital stay extended 1 day (OR, 1.46; 95% CI, 0.7-3.2; $P = .34$).

Postoperative complications are listed in Table 5. There were 8 total complications for the PVS group, of which 5 were grade 1 and 3 were grade 2 based on the Clavien-Dindo classification. For the 10 complications in the MUS group, 6 were grade 1, 1 was grade 2, and 3 were grade 3. Voiding difficulty occurred in 4 and 3 women in the PVS and MUS group, respectively. In the PVS group, 1 patient presented in urinary retention at 3 months postoperatively and was occasionally performing self-intermittent catheterization (SIC) at last follow-up (20.6 months). She was content and did not want further workup or treatment that could compromise her continence, whereas the 3 remaining patients had retention (performed SIC) that was transient and which resolved within 1 month of the surgery. In the MUS group, 1 required transvaginal sling incision at 2.5 weeks postoperatively, 1 had prolonged urinary retention and was performing SIC at last follow-up (19.9 months) but was not interested in further surgery that could compromise her continence, whereas the remaining patients had retention that resolved after 4 months without intervention. There was 1 midline mesh exposure that was managed with sling trimming in the office and estrogen cream. One woman in the MUS group presented on the first postoperative day with a urine leak from the right puncture site and was found to have an intravesical mesh perforation from a missed trocar puncture. She underwent partial sling removal through an open retropubic approach and was continent at last follow-up. There was 1 superficial wound infection in the PVS group, which was managed conservatively and nonoperatively. No perioperative blood transfusions were administered in either group, and no harvest site hernias or other complications were noted.

## COMMENT

In light of the FDA notifications, there has been controversy surrounding all transvaginal mesh, despite a very supportive 2011 FDA advisory panel on surgical mesh for the treatment of SUI in women.[9] Understandably, women may be concerned with the implantation of mesh. Although PVS is an option for the surgical treatment of female SUI, little data are available comparing the 2. Novara et al[17] performed a meta-analysis comparing MUS with PVS and demonstrated similar efficacy, although the studies were few and of poor methodologic quality.[17] More recently, Sharifiaghdas et al randomized 100 women with SUI to either autologous rectus fascia PVS or tension free vaginal tape (TVT).[18] Thirty-nine percent were lost to follow-up by 1 year. Of those who reached 1 year of follow-up, the mean follow-up time for the PVS and MUS was 40 and 38.5 months, respectively.

**Table 3.** Questionnaire outcomes

| Outcome | PVS | | | MUS | | |
|---|---|---|---|---|---|---|
| | Preoperative | Postoperative | *P* Value* | Preoperative | Postoperative | *P* Value* |
| SEAPI total | 5.5 | 2.09 | <.001 | 6 | 2.29 | <.001 |
| IIQ-7 | 7.2 | 1.85 | <.001 | 7.2 | 1.85 | <.001 |
| UDI-6 | 8.5 | 2.29 | <.001 | 9.1 | 2.34 | <.001 |
| VAS | 2.3 | 8.46 | <.001 | 2.3 | 8.44 | <.001 |

Abbreviations as in Table 1.
* Wilcoxon signed rank test.

**Table 4.** Postoperative clinical outcomes

| Outcome | PVS | MUS | *P* Value* |
|---|---|---|---|
| SUI cure rate (%) | 75.8 | 80.9 | .38 |
| Pads/d (mean) | 0.63 | 0.63 | .28 |
| De novo UUI (%) | 16.7 | 33.3 | .24 |
| UUI persistence (%) | 58.2 | 57.9 | .97 |
| UUI resolution (%) | 41.8 | 42.1 | .97 |
| Length of hospitalization, d, (mean) | 1.17 | 1.16 | .9 |

SUI, stress urinary incontinence; UUI, urge urinary incontinence; other abbreviations as in Table 1.
* Simple logistic regression.

**Table 5.** Postoperative complications

| Complication | PVS | MUS | *P* Value* |
|---|---|---|---|
| Infectious | | | .22 |
| Wound | 1 | 0 | |
| UTI | 2 | 0 | |
| URI | 0 | 1 | |
| Voiding difficulty, n (%) | 4 (4.4) | 3 (2.7) | .52 |
| Pain | 0 | 2 | NA |
| Mesh exposure | 0 | 1 | NA |
| Miscellaneous | | | .41 |
| PE | 0 | 1 | |
| Respiratory insufficiency | 1 | 0 | |
| Fall | 0 | 1 | |
| Urine leak | 0 | 1 | |
| Total, n (%) | 8 (8.8) | 10 (9.1) | .94 |

PE, pulmonary embolus; NA, not available; URI, upper respiratory infection; UTI, urinary tract infection; other abbreviations as in Table 1.
* Fisher exact test.

Nearly 40% had prior anti-incontinence surgery. SUI cure rates were similar between both groups. Mean operative time (45 vs 80 minutes; $P = .01$) and hospital stay (2 vs 5 days; $P = .001$) favored the TVT group, whereas bladder penetration occurred more often in the TVT group (6 vs 2 cases; $P = .05$). One and 2 patients required sling release for urinary retention in the TVT and PVS group, respectively. De novo UUI was similar between both groups. No wound complications nor mesh exposure were noted, but 1 patient in the PVS group developed an incisional hernia requiring repair.[18] Our long standing practice (which predates the 2008 FDA notification) to offer both PVS and MUS as a primary treatment to patients who would otherwise be considered good candidates for MUS allows for study in a contemporary series. SUI cure rates were similar in both treatment groups. Although not randomized and no metric was used to assess a patient's choice of procedure, the fact that mesh usage for SUI has not declined in our practice is suggestive of balanced patient counseling and informed consent, with no obvious procedure bias on the part of the operator.

Prolonged urinary retention occurs in a median of 8% (4-15) and 3% (2-4) after PVS and MUS, respectively.[19] Although our MUS retention data are consistent with published reports, the PVS group was lower. There are several possible reasons. This single-surgeon series is from a fellowship-trained urologist practicing at a high-volume referral center, and most contemporary series have shown a trend between lower retention rates with increasing surgeon experience.[20] Indeed, in a review of >500 cases of PVS performed, Blaivas et al[21] had an incidence of long-term urethral obstruction requiring surgery or intermittent catheterization in 1% of cases. Second, there is the possibility of procedure selection bias although this does not appear to be the case as the similar baseline patient and clinical findings in Tables 1 and 2 suggest. Third, most series for PVS either allow concomitant prolapse surgery or are for recurrent SUI, which may artificially elevate the incidence of retention. This would make comparisons to our study cohort, a surgically naïve group, difficult. As an example, the Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) noted a surgical revision rate of 6.1% for postoperative voiding dysfunction, but concomitant prolapse repair was performed in a majority and 13% had prior anti-incontinence surgery.[22] Our de novo UUI rate was higher for the MUS group (33.3%) than for the PVS group (16.7%) but was not statistically significant ($P = .24$). This difference and the higher rate for both groups than historically reported is likely because of a small denominator, resulting from the high prevalence of UUI at baseline in this study.

Each procedure is associated with unique complications that can be potentially serious. The American Urological Association panel cited a wound complication of 8% for PVS, but this figure encompasses a wide variety of ways authors name, describe, and classify them.[19] In the SISTEr trial, Albo et al[22] noted a 3.4% incidence of serious wound complications that required surgical intervention but did not provide further details past this. In Blaivas and Chaikin's[21] series of >500 patients who underwent PVS, they noted a 1% rate each for wound infection and incisional hernias. In another large series,

Morgan et al[20] noted 2 incisional hernias (0.8%) in their cohort of 247 patients but no mention was made of wound issues aside from this. Similarly, we noted 1 (1.1%) wound infection that was managed non-operatively, and no incisional hernias were noted. MUS can be associated with the unique complication of mesh exposure, which can result in serious sequelae not experienced by patients who undergo traditional repair. Reported rates vary between 0% and 25%, with a median in the 7% range.[17,23] In line with this wide range, 1 patient (0.9%) in our MUS group had a mesh exposure, which was managed with trimming and estrogen cream.

The strengths of the study lie in its design, with the FDA notification and the subsequent concern over mesh providing a unique opportunity to compare the efficacy and morbidity of the PVS in a surgically naïve group that, in many practices, would be typically considered a good candidate for an MUS, and who before the notification would have likely received one without being offered another option. An additional strength of the study is its prospective and medium-term follow-up (>1 year) with subjective and objective criteria used to define success and validated questionnaires used to describe impact on quality of life. In terms of drawbacks, although the serious complications that contribute to the higher morbidity traditionally associated with PVS were accounted for, we did not assess pain complaints postoperatively with pain scores nor use of pain medication; however, this may be confounded by a majority from both the groups undergoing concomitant hysterectomy. The lack of patient choice assessment on procedure type obscures surgeon selection bias on procedure preference, which may influence patient decision making, especially in this non-randomized study. However, the fact that our mesh use for SUI has not changed predating 2008 suggests a fair and honest dialogue with patients regarding the risk and benefits of each procedure, despite the current climate concerning transvaginal mesh. It also must be kept in mind that these women were treated for their SUI by a high-volume fellowship-trained surgeon at a tertiary-care referral center so these results may not translate to other settings.

## CONCLUSION

In this contemporary cohort of women with SUI considered suitable candidates for either PVS or MUS, both offer comparable efficacy and complication rates. PVS may be safely offered to patients who would otherwise be good candidates for MUS if they are concerned with the implantation of mesh.

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